

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS
PRODUCTS LIABILITY LITIGATION

----- MDL No. 2327

THIS DOCUMENT RELATES TO:

Huskey et al. v. Ethicon et al. Case No. 2:12-CV-05201

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTIONS IN LIMINE

Plaintiffs Jo and Allan Huskey ("Plaintiffs") state as follows in support of their Motions in Limine:

MOTION IN LIMINE NO. 1: to Exclude Evidence FDA 510(k) Evidence

Plaintiffs' previously filed their "Motion in Limine No. 1: To Exclude FDA 510(k) Evidence" on April 10, 2014. [Dkt. No. 139]. That motion was granted pursuant to this Court's order of May 12, 2014. [Dkt. No. 223].

MOTION IN LIMINE NO. 2: To Exclude Evidence of Certain Medical Conditions of Jo Huskey

Plaintiffs anticipate that Defendants will attempt to enter testimony or evidence relating to a number of Jo Huskey's previous medical conditions and medical procedures that are irrelevant to the alleged injuries in this case. Defendants cannot offer *any* expert opinion these conditions are causally related to Mrs. Huskey's current injuries. To the contrary, Defendants' sole specific causation expert, Christina Pramudji M.D. ("Dr. Pramudji"), excludes them as a cause or contributing cause, or her related testimony has been excluded by this Court [Dkt. No. 271]. Accordingly, any evidence of these past medical conditions or procedures is irrelevant to Plaintiffs' claims and is unduly prejudicial in violation of Federal Rules of Evidence 402 and 403.

Plaintiffs seek to exclude at trial all evidence of the following medical conditions and procedures: (1) hypothyroidism, (2) appendectomy, (3) cholecystectomy, (4) left shoulder injury and surgery, (5) 2009 vehicle accident,¹ (6) fibroids and resulting hysterectomy,² (7) endometriosis,³ (8) interstitial cystitis, (9) emotional stress, and (10) prior back pain and two back surgeries in 1997 and 2000.⁴ Though Dr. Pramudji identified various medical conditions and how they may be related to Mrs. Huskey's injuries, she has either specifically excluded or affirmatively abandoned these conditions and procedures as a potential cause of Mrs. Huskey's injuries, or her testimony has been excluded by this Court. Defendants therefore have no expert to offer the opinion that any of these conditions are a potential cause of Mrs. Huskey's current condition. Primarily by Defendants' own admission, these are not relevant to Mrs. Huskey's claims and are therefore inadmissible pursuant to F.R.E. 402.

When evaluating whether to allow this evidence at trial, this Court must weigh Defendants' need for the evidence against the harmful consequences that may result from its admission. *Carnell Contr. Corp. v. Danville Redevelopment & Hous. Auth.*, 745 F.3d 703, 719 (4th Cir. 2014). A primary danger is unfair prejudice, which "refers to an undue tendency of evidence to influence a jury to make a decision for reasons unrelated to the probative value of the

¹ Dr. Pramudji was asked at her deposition about any and all factors that she believes is causing or contributing to Mrs. Huskey's current pain. After discussing a number of conditions, she confirmed that there was nothing else she believes to be causally related. See Exhibit ("Ex.") 1, Deposition of Christina Pramudji M.D., at 196:4-199:6; 205:10-210:15. Dr. Pramudji does not find the following to be causally related to Mrs. Huskey's injuries: hypothyroidism, appendectomy, cholecystectomy, left shoulder injury and surgery, and a 2009 vehicle accident. See *id.*

² Dr. Pramudji does not opine that fibroids prior to Mrs. Huskey's hysterectomy are related to her current injuries in either her report or deposition. Dr. Pramudji also states that it does not sound like scar tissue from Mrs. Huskey's hysterectomy is at issue here. *Id.* at 215:5-8

³ Defendants concede that Dr. Pramudji will not discuss endometriosis as a contributing cause of Mrs. Huskey's condition and pain within Defendants' Memorandum in Opposition to Plaintiffs' Motion to Exclude Certain Opinions and Testimony of Christina Pramudji, M.D. [Dkt. No. 209]. This Court then excluded opinions related to Endometriosis. [Dkt. No. 271].

⁴ This Court has excluded Dr. Pramudji's opinions related to interstitial cystitis, emotional stress, and two back surgeries. [Dkt. No. 271]. Defendants accordingly have no expert to opine that these conditions are causally related to Mrs. Huskey's injuries.

evidence.” *Id.* If Defendants cannot show that these conditions are causally related to Mrs. Huskey’s injuries, then they have no probative value to this case. Further, allowing evidence of these unrelated conditions and injuries would create a substantial risk of confusion the jury in violation of Rule 403. The jury might mistakenly connect those injuries to her current symptoms, or draw inferences related to her medical care and treatment. Therefore, admission of such evidence would be unfairly prejudicial to Plaintiffs.

For the reasons stated above, Plaintiffs respectfully request that this Court enter an order precluding evidence at trial regarding the medical conditions and injuries that are outlined in this Motion.

MOTION IN LIMINE NO. 3: To Exclude Evidence of Mrs. Huskey’s Prior Divorce

Defendants recently obtained the 2001 court file pertaining to Mrs. Huskey’s divorce from Mr. Brett Marshall (“Mr. Marshall”). Plaintiffs assume that Defendants intend to offer evidence of Mrs. Huskey’s divorce, including the contents of this file, at trial. The use of this information would be an improper attack on Mrs. Huskey, and admission of the file would be improper (for multiple reasons) under the Federal Rules of Evidence. Evidence related to Mrs. Huskey’s divorce, including this file, should be excluded in its entirety.

I. This Evidence Is Irrelevant and Inadmissible Under Fed. R. Evid. 401 and 402

Mrs. Huskey’s divorce proceedings, including the court file, have absolutely no bearing on any facts, claims or defenses in this case.⁵ Mrs. Huskey was no longer with Mr. Marshall at any time relevant to her claims. Indeed, the TVT-O was not implanted until almost eight years after the marriage was dissolved on April 29, 2003. The court file contains over 800 pages of

⁵ Evidence must have a tendency to make a fact of consequence more or less probable. *See* Fed. R. Evid. 401.

documents, including financial statements and custodial arrangements.⁶ These documents date back to 2001 and almost entirely pre-date this trial by at least ten years. The contents of this file are entirely irrelevant to whether or not Defendants designed, manufactured, marketed, and distributed a defective product that injured Mrs. Huskey. Further, any financial documents contained in this file are irrelevant to any calculation of damages.

II. The Divorce File Contains Inadmissible Hearsay under Fed. R. Evid. 801

Mrs. Huskey's divorce file contains documents such as letters written by Mr. Marshall to Mrs. Huskey making various allegations (which are disputed by Mrs. Huskey).⁷ It also includes similar letters written by Mr. Marshall's counsel.⁸ These letters fall squarely into the definition of hearsay, as they are out-of-court statements offered to prove the truth of the matters asserted therein. In addition to this correspondence, Plaintiffs assert that any pleading filed by or on behalf of Mr. Marshall also constitutes hearsay.⁹ Another court's file stamp does not render these documents admissible into evidence. Federal courts acknowledge that statements made in pleadings are, in fact, inadmissible hearsay under Federal Rule of Evidence ("Fed. R. Evid.") 801.¹⁰ Any pleadings filed on behalf of Mr. Marshall; any letters written by Mr. Marshall and/or

⁶ See Ex. 2, Excerpts from *Marshall v. Marshall*, 01-D-447 (Cir. Ct. Macon Co.) Court File. Due to the large size of the divorce file at issue, Plaintiffs have only included portions of the file—removing many duplicates, financial documents, home appraisal documents, tax forms and copies of case law from the version electronically filed as Ex. 2 to this Motion. Plaintiffs assert that such documents are also irrelevant to any claims or defenses in this case. Plaintiffs do not claim any privilege for these (already) publically available documents, and can provide them to the Court upon request.

⁷ See e.g., Ex. 2 at HUSKEYJ_LERCC_LEG00511-17, 520-25, 528-31, 538-40, 543-45.

⁸ See e.g., Ex. 2 at HUSKEYJ_LERCC_LEG00462-64.

⁹ See *Century "21" Shows v. Owens*, 400 F.2d 603, 609-10 (8th Cir. 1968) (divorce petitions were refused into evidence in a personal injury action because they constituted hearsay and had no probative value).

¹⁰ See *Friends of Milwaukee's rivers v. Milwaukee Metro. Sewerage Dist.*, No. 02-C-0270, 2006 U.S. Dist. LEXIS 68627, at*8 (E.D.WI., Sept. 20, 2006) (confirming that courts have found complaints to be inadmissible hearsay when offered to prove the truth of their contents); *Century "21" Shows*, 400 F.2d at 609-10; *In re Harmony Holdings, LLC*, 393 B.R. 409, 414-15, 443 (Bankr. D.S.C. Sept. 11, 2008) (the court held that the admission into evidence of facts contained within a pleading filed with a court must also be evaluated using evidentiary rules such as hearsay, and that the mere fact that a document is filed with the Court does not bolster its credibility.).

his attorney; and any other documents of this kind in the court file from the divorce should be excluded on these grounds.

III. Evidence of Mrs. Huskey's Divorce is Inadmissible under Fed. R. Evid. 608(b)

This evidence is also improper for any asserted purpose relating to Mrs. Huskey's truthfulness. Under Fed. R. Evid. 608(b): "...extrinsic evidence is not admissible to prove specific instances of a witness's conduct in order to attack or support the witness's character for truthfulness." Even for use on cross examination, the admission of this evidence is within this Court's discretion with the safeguard that any instances not be remote in time. *See* Fed. R. Evid. 608, Advisory Committee Notes. Further, the Advisory Committee cautions that when presented with this type of evidence, the "possibilities of abuse are substantial" and Rule 611 mandates that courts protect witnesses from harassment and undue embarrassment. *Id.* Almost all contents of this court file are over ten years old, and the divorce petition was filed in 2001. The highly prejudicial nature of this evidence poses the exact risk of abuse warned of by the Advisory Committee. Evidence of Mrs. Huskey's divorce is extremely remote in time to both Mrs. Huskey's implant and this trial, it lacks probative value, and it poses a risk of abuse and harassment. These significant concerns warrant the exclusion of this evidence.

IV. Evidence of Mrs. Huskey's Divorce is Unduly Prejudicial under Rule 403

The information contained in Mrs. Huskey's divorce file, read together or in pieces, simply cannot accurately reflect the circumstances of her marriage and subsequent divorce from Mr. Marshall. This file is replete with disputed facts and allegations. The admission of evidence of Mrs. Huskey's divorce would create a complete sideshow at trial, and potentially hours of questioning related to the details of her prior divorce and the context of various documents—which have absolutely nothing to do with this case. This is almost certain to mislead the jury,

cause great confusion, cause significant delay, and severely prejudice Mrs. Huskey. Therefore, evidence of Mrs. Huskey's divorce (and the divorce file) should be excluded under Rule 403.¹¹ Given the nature of divorce generally and the circumstances in Mrs. Huskey's case, this evidence is precisely the type of evidence that Rule 403 is meant to exclude.

As such, Plaintiffs move the Court for an order excluding all evidence related to Mrs. Huskey's divorce from Mr. Marshall, including the contents of the related case file.

MOTION IN LIMINE NO. 4: To Exclude Email from Jo Huskey where She Comments about Defense Counsel

Plaintiffs seek to exclude a May 28, 2013, email written by Mrs. Huskey—shortly after her deposition—in which she makes a comment about one of Defendants' attorney's conduct at her deposition. More specifically, the email contains the following statement by Mrs. Huskey:

I have to watch what I write now as to avoid a certain subject unless I talk to you personally ha! take that you wicked evil beeach like attorney who put me through hell!¹²

Plaintiffs move to bar the admission of this email as both irrelevant and prejudicial.¹³

This statement (about Mrs. Huskey's personal perception of having to sit for her deposition) is completely irrelevant to the claims and defenses in this case. It simply has no bearing on whether or not Defendants designed, manufactured, marketed, and distributed a defective product that injured Mrs. Huskey. Indeed, evidence relating solely to a party's

¹¹ Evidence is unfairly prejudicial when there is a genuine risk, disproportionate to any probative value of the proffered evidence, that emotions of the jury may be excited to irrational behavior. *United States v. Mohr*, 318 F.3d 613, 618 (4th Cir. 2002) (citing *United States v. Powers*, 59 F.3d 1460, 1467 (4th Cir. 1995)). The risk here of a jury responding in such a fashion is substantial, and this evidence has no probative value.

¹² See Ex. 3, May 28, 2013, Email from Jo Huskey to Nancy Davidson, HUSKEYJ_EMAILS_0091.

¹³ Plaintiffs' counsel certainly do not condone this type of conduct or language directed (by their client) at opposing counsel, and regret that this statement was ever made.

litigation conduct has no bearing on whether a plaintiff was injured as a result of a defective product.¹⁴ Therefore, it should be excluded as irrelevant.¹⁵

Additionally, the Court should exclude this email under Rule 403 because its probative value is substantially outweighed by a danger of unfair prejudice to Plaintiffs.¹⁶ Evidence relating to litigation conduct such as this “lacks probative value and carries a high risk of prejudice.”¹⁷ The statement is clearly prejudicial due to the inflammatory nature of the subject (the litigation process and the perceived conduct of defense counsel), as well as the inflammatory nature of the language itself. The email was written at an emotionally-charged time when Mrs. Huskey was frustrated by the private nature of the inquiries required by cases such as these. The admission of this email would prejudice Mrs. Huskey by forcing her to be confronted with emotionally-charged and inflammatory statements unrelated to the issues in this case, and would also run the risk of wasting time and misleading the jury with immaterial information.

As such, Plaintiffs move the Court for an order excluding this May 28, 2013, email in its entirety. In the alternative, should the Court find that any other portion of that email is relevant and admissible for some purpose, Plaintiffs respectfully request that the sentences quoted above be redacted and excluded if the remainder of the email is entered into evidence.

MOTION IN LIMINE NO. 5: To Exclude Certain Statements from Jo Huskey’s Journal Blaming and Criticizing Dr. Byrkit

Plaintiffs seek to exclude statements contained in Plaintiff Jo Huskey’s journal. In that journal, Mrs. Huskey makes several statements indicating that, at the time, she (mistakenly)

¹⁴ See, e.g., *Timberlake Constr. Co. v. United States Fidelity & Gaur. Co.*, 71 F.3d 335, 340-41 (10th Cir. 1995); *Oki America, Inc. v. Micortech Int’l, Inc.*, 872 F.2d 312, 314 (9th Cir. 1989).

¹⁵ To be admissible, evidence must have some logical tendency to prove or disprove a fact—i.e., to create a reasonable inference as to the probability of lack of probability of that fact. See *A.I. Credit Corp. v. Legion Ins. Co.*, 265 F.3d 630, 638 (7th Cir. 2001); *U.S. v. Kaplan*, 490 F.3d 110, 120-21 (2nd Cir. 2007).

¹⁶ See Fed. R. Evid. 403.

¹⁷ *Timberlake*, 71 F.3d at 341.

believed that her medical treatment was inadequate.¹⁸ Plaintiffs move to bar the admission of any such statements as both irrelevant and prejudicial. Because no party is claiming that Dr. Byrkit was negligent, any past statements about the quality of her care are wholly irrelevant.

The subject journal entries contain statements made by Mrs. Huskey at various times in 2011 in which she notes her personal feelings regarding her physicians and treatment. These statements include, but are not limited to: “[w]hy didn’t she [Dr. Byrkit] assess my anatomy and adjust my surgery to complete it correctly”; “[o]nce again she lied to me and stated that [pain associated with scar tissue] would not be an issue”; “[i]s this because the mesh was not placed deep enough”; “[i]sn’t it negligence for Dr. Byrkit to knowingly deny what has been not only proven, but has effected numerous amounts of women with significant problems”; “...she [Dr. Byrkit] just continued to lie to me”; “Dr. Byrkit is totally responsible for not placing the mesh properly”; and “[t]his is what I have thought all along—she did not know how to place the mesh and it wasn’t placed right.”¹⁹

These statements are in no way relevant to the issues in this case. Neither Plaintiffs nor Defendants are alleging that Dr. Byrkit has committed any malpractice or done anything wrong in this case. Moreover, Illinois courts have routinely held that evidence of another person’s liability is irrelevant to the issue of defendant’s liability.²⁰ As such, evidence of Dr. Byrkit’s liability is simply irrelevant to Defendants’ liability. These statements made by Mrs. Huskey simply do not have any bearing on whether or not Defendants designed, manufactured, marketed, and distributed a defective product which injured Plaintiff Jo Huskey, and therefore these statements should be excluded as irrelevant.²¹

¹⁸ See Ex. 4, Journal Entries of Plaintiff Jo Huskey.

¹⁹ *Id.*

²⁰ *Leonardi v. Loyola University of Chicago*, 658 N.E.2d 450, 455 (Ill. 1995).

²¹ See Fed. R. Evid. 401

Moreover, Defendants have admitted that there is no scientific or medical relevance to the frustrated-statements in Mrs. Huskey's Journal. In Defendants' responses to Plaintiffs' Requests for Admissions, Defendants noted that "Ethicon admits that Dr. Byrkit was not negligent in administering informed consent to Mrs. Huskey and that the informed consent conformed to the standard of care."²² Furthermore, Defendant Ethicon admitted "that Dr. Gretchen Byrkit was not negligent in the implantation of TVT-O Device in Plaintiff."²³ The issue of whether or not Dr. Byrkit conformed to the standard of care in this case is not at issue; and therefore, Plaintiff's statements in which she alleges that Dr. Byrkit failed to conform to this standard of care are irrelevant.

Under Illinois law, laypersons are normally not qualified to evaluate professional medical conduct.²⁴ Here, Mrs. Huskey is neither a doctor nor a medical expert, and she is not qualified to evaluate professional medical conduct. Plaintiff's comments that her mesh was incorrectly placed are unqualified evaluations of the professional medical treatment that she has received. So, even if the standard of care provided by Dr. Byrkit *was* at issue (which it is not), Mrs. Huskey would not be qualified to evaluate her own medical care.

Moreover, the Court should exclude this evidence under Rule 403 because its probative value is substantially outweighed by a danger of unfair prejudice or misleading the jury. *See* Fed. R. Evid. 403. As stated above, the statements in the journal have no probative value because no party has made the care provided by Dr. Byrkit an issue in this case. And the journal statements are clearly prejudicial due to their inflammatory nature. Mrs. Huskey accuses Dr. Byrkit of lying and blames Dr. Byrkit of failing to meet the medical standard of care—statements that neither side claim as true. The fact that many of these statements were written in all capital

²² Ex. 5, Responses of Ethicon, Inc. to Requests for Admission.

²³ *Id.*

²⁴ *See Addison v. Whittenberg*, 529 N.E.2d 552, 556 (1988).

letters, and the language itself, indicate that these statements were made at an emotionally-charged time when Mrs. Huskey was confused and frustrated about the causes of her pain. The admission of these statements would prejudice Mrs. Huskey by forcing her to be confronted with emotionally-charged and inflammatory statements unrelated to the issues in this case. The admission of the statements at issue would also run the risk of wasting time and confusing and misleading the jury with immaterial information. Indeed, these statements would cause the jury to evaluate the care provided by Dr. Byrkit—a non-issue that is outside the scope of this case.

While the issues involved in this case are numerous and complex, the liability and care provided by Dr. Byrkit are not among those issues. Plaintiffs ask the Court to bar Defendants from introducing the inflammatory statements in Plaintiff’s personal journal.

MOTION IN LIMINE NO. 6: To Exclude Certain Irrelevant and Prejudicial Domestic Circumstances in Jo Huskey’s Past

Plaintiffs respectfully request that this Court exclude evidence about Plaintiff Jo Huskey’s life that is unrelated to her surgery to implant the TVT-O. Under Federal Rule of Evidence 402, evidence is only admissible if it is relevant.²⁵ Evidence is relevant under Rule 401 where: “(a) it has any tendency to make a fact more or less probable than it would be without the evidence; and b) the fact is of consequence in determining the action.”²⁶ Under Rule 401, the following aspects of Mrs. Huskey’s life are irrelevant, and therefore, inadmissible:²⁷

- Mrs. Huskey’s treatment with a therapeutic social worker, Ruth Teel, regarding any matter not related to Mrs. Huskey’s SUI surgery and subsequent permanent injury therefrom;²⁸
- Mrs. Huskey’s first marriage, and any physical, mental, and emotional abuse she suffered during it, and/or her resulting divorce;²⁹

²⁵ See Rules 401 and 402.

²⁶ See Rule 401(a)(b).

²⁷ *Id.*

²⁸ See Ex. 6, May 24, 2013 Deposition of Jo Huskey (“Huskey Dep.”) at 39:14-42:6; 454:12-455:11.

- Mrs. Huskey's strained relationship with her adult children;³⁰
- Mrs. Huskey's family history of depression,³¹ and/or her own bouts with or treatments for depression unrelated to her mesh implant or related complications;³²
- Mrs. Huskey's history of being overweight as a teenager and any mental health issues resulting therefrom.³³

None of the foregoing issues are relevant to whether Mrs. Huskey has suffered severe, debilitating, and permanent injury as a result of receiving the TVTO device. Indeed, not one of Defendants' experts have even attempted to link any of these circumstances in Jo Huskey's past to her injuries, her current condition or her claims in this case. Therefore, there is no valid claim that these issues are relevant, and any reference to them should be excluded.³⁴

Even if this Court concludes that the above-referenced testimony is relevant,³⁵ references to these issues should be excluded under Rule 403 because "its probative value is substantially outweighed by [the] danger of . . . unfair prejudice . . .".³⁶ In short, relevant evidence must be excluded as having unfair prejudice if "the possibility [exists] that the evidence will excite the jury to make a decision on the basis of a factor unrelated to the issues properly before it."³⁷

Here, the facts and circumstances listed above are prejudicial and should be excluded at trial. In particular, the testimony regarding Mrs. Huskey's allegedly abusive first marriage (and

²⁹ Ex. 6 (Mrs. Huskey Dep.), 89:20-96:22; 225:20-23; 299:9-300:1; Ex. 7 Deposition of Allan Huskey ("Mr. Huskey Dep."), 22:21-23:10; 87:5-19; 183:16-19); Ex. 8, (Mrs. Teel Dep.) 45:2-48:19; 76:13-77:19.

³⁰ Ex. 6 (Mrs. Huskey Dep.), 88:24-89:19; 91:13-92:10; 96:24-98:11; Ex. 7 (Mr. Huskey Dep.), 21:6-18; 87:20-88:6.

³¹ Ex. 6 (Mrs. Huskey Dep.), 234:8-11; 235:6-9.

³² Ex. 6 (Mrs. Huskey Dep.), 234:11-235:6; 235:9-13; 236:8-245:5; 286:6-21; Ex. 7 (Mr. Huskey Dep.), 70:16-74:6; 81:24-83:8; 86:20-87:3; Ex. 8, Deposition of Ruth Teel, 21:3-24:11.

³³ Ex. 6 (Mrs. Huskey Dep.), 297:15-298:7; 298:14-301:8; 301:12-303:24; Ex. 7 (Mr. Huskey Dep.) 77:8-78:7).

³⁴ See Rule 401.

³⁵ See *Hodges*, 886 F. Supp. 352, 356 (S.D.N.Y. 1995) (before Rule 403 is triggered, evidence must be found to be relevant) (In excluding psychiatric expert, the court held that even if a nexus existed between Hodges' past mental health symptoms and his credibility, "the proffered mental health records and the expert testimony which is largely based on these records raise several of the risks enumerated by Rule 403.").

³⁶ Rule 403.

³⁷ See *U.S. v. Singer*, Crim. No. 9:05-cr-00928, 2009 WL 519 4990 at *2 (D.S.C. December 22, 2009) (citing to and quoting from *Mueller v. Princess Anne Volunteer Fire Co. Inc.*, 853 F.2d 1130, 1134 (4th Cir. 1988)).

divorce), her strained relationship with her adult children, and her family (and possibly personal) history of depression could take the jury's focus away from the facts that are central to the issues in this case. As such, even if the Court believes that the aforementioned issues are relevant, it should, nevertheless, exclude any reference to those matters under Rule 403.

MOTION IN LIMINE NO. 7: To Limit Treating Physicians' Testimony to Facts of the Case and their Treatment of Plaintiff

Plaintiffs have moved separately to exclude certain testimony of Mrs. Huskey's treating physician, Elizabeth Mueller, M.D., that is far beyond the scope of her treatment of Plaintiff in this case. However, Plaintiffs are aware of testimony by Mrs. Huskey's other treating physicians that also exceeds their scope as fact witnesses in this case. As such, Plaintiffs move for an order generally limiting all treating physicians' testimony to facts of the case and their treatment of Mrs. Huskey.

This Court and others have noted that a treating physician may testify *only* to matters within the scope of her treatment of a patient/plaintiff.³⁸ Anything beyond that scope is considered expert opinion and the physician in question must submit a proper expert report pursuant to Rule 26(a)(2)(B).³⁹ Mrs. Huskey's treating physicians have not submitted expert reports, and have not submitted summaries of their opinions as non-retained or non-reporting experts under Rule 26(a)(2)(C).⁴⁰ Therefore, Mrs. Huskey's treating physicians' opinions may

³⁸ See *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 615 (S.D.W.Va. 2013) ("The inquiry is whether the treating physician's testimony addresses knowledge gained and opinions formed during the course of treatment; or whether the treating physician seeks to offer opinions which address information outside the scope of treatment."); *Hinkle v. Ford Motor Corp.*, C. A. No. 3:11-24-DCR, 2013 WL 1992834 at *5-6 and nn. 4, 7 (E.D.Ky. May 13, 2013) (limiting the treating physicians' testimonies to "the 'permissive core' of their treatment of plaintiff."); *Bekaert Corp., v. City of Dyersburg*, 256 F.R.D. 573, 575-76 (W.D.Tenn. 2009) ("As an unretained expert, a treating physician may testify to events and opinions arising directly through her treatment of the patient.").

³⁹ See *National R.R. Passenger Corp., v. Railway Express, LLC*, 268 F.R.D. 211, 216 (D.Md. 2010) (holding that "a party may not circumvent the requirements of Rule 26 by employing a witness like a treating physician who treated an injured party, to provide testimony extending into a classic expert opinion regarding causation and prognosis. ").

⁴⁰ See e.g., *Certain Interested Underwriters at Lloyd's London v. Cooper*, C/A No. 3:10-cv-01382-JFA, 2012 WL 554577 at *6 (D.SC Feb. 21, 2012).

include only those items directly related to their limited treatment of Mrs. Huskey—and may not include any of the extraneous and irrelevant opinions.⁴¹

MOTION IN LIMINE NO. 8: To Exclude Reference to Jo Huskey’s Difficult Childbirth and Forceps Delivery

Plaintiff Jo Huskey moves this Court *in limine* to exclude any reference to a difficult childbirth that she experienced, which has no relevance to the present dispute

I. Reference to Mrs. Huskey’s Difficult Childbirth is Irrelevant

Any reference to Mrs. Huskey having experienced a difficult childbirth or requiring the use of forceps during childbirth is irrelevant under Fed. R. Evid. 401. None of Defendants’ experts have opined that Mrs. Huskey’s difficult delivery caused or contributed to her present injuries. Dr. Pramudji is the only defense expert who discusses Mrs. Huskey’s forceps delivery in any detail. She notes in her expert report that Mrs. Huskey has a history of a forceps delivery with “significant tears and repair;” however, she fails to link this past condition with Mrs. Huskey’s present condition—and certainly does not offer an opinion to that effect.⁴² Additionally, Dr. Pramudji does not raise the subject of Mrs. Huskey’s forceps delivery in her supplemental expert report.⁴³

Although several of Mrs. Huskey’s treating physicians reference her medical history of having a difficult forceps delivery with her first child, they do not sufficiently explain why or how this information relates to her present pelvic pain. Dr. Ogunleye testified that a forceps delivery *can* affect the pelvic floor muscles and it *could* have a negative impact on the pelvic

⁴¹ See also *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 616 (excluding “expert opinions, if any on product design . . . [and] other opinions formed outside of the treating physician’s care and treatment of the bellwether plaintiffs. . . . These latter opinions are fraught with reliability and relevancy issues.”).

⁴² Ex. 9, Expert Report of Christina Pramudji, M.D., p. 45.

⁴³ See Ex. 10, Christina Pramudji Supplemental Expert Report (Jo Huskey IME).

floor.⁴⁴ He also testified that the delivery “*could* make the pelvic floor muscles weaker going forward” and that these conditions could manifest later on.⁴⁵ While Dr. Ogunleye testified that Mrs. Huskey’s forceps delivery could weaken her pelvic floor muscles, he did not attribute the delivery to her present pain. In fact, he ruled out the possibility that a forceps delivery could have caused her vaginismus.⁴⁶ He testified that he would sometimes see vaginismus in:

women who have never had sex before and they have a lot of pelvic floor muscle tightness, and we see it in those women because the levator ani is just totally contracted, and it’s just totally very tight, so that would be a reason why that would happen but not in women who have had sex over long period of time, who have had those kind of vaginal deliveries, who’ve definitely had a forceps delivery. All those would have probably totally broken down. So for someone to have that much later on in life, very likely it would be spasm either from scar tissue or a foreign body.⁴⁷

Since Dr. Ogunleye actually attributed her vaginismus to something else (either scar tissue or a foreign body), any reference to Mrs. Huskey having a difficult forceps delivery has no relevance to the issues before the Court.

Dr. Fitzgerald, another treating physician, testified that Mrs. Huskey’s tears and repairs during her forceps delivery would have been something she would have considered significant in assessing Mrs. Huskey’s pain; however, she did not explain why this would be significant.⁴⁸ Further, Dr. Mueller testified that even if she had known that Mrs. Huskey had previously reported having a significant tear and repair with at least one of her pregnancies, she would not have considered it to be significant information.⁴⁹ Considering that neither Mrs. Huskey’s treating physicians nor Defendants’ experts attribute her chronic pelvic pain to her difficult delivery, any reference to her difficult delivery should be excluded as irrelevant.

⁴⁴ Ex. 11, Deposition of Dr. Dele Ogunleye, 17:19-19:22 (*emphasis added*).

⁴⁵ *Id.* at 19:23-20:12 (*emphasis added*).

⁴⁶ Dr. Ogunleye defines this as “pain or difficulty with sexual activity either because of scarring or because of pain generally.” *Id.* at 50:21-25.

⁴⁷ *Id.* at 58:17-59:8.

⁴⁸ Ex. 12, Deposition of Dr. Colleen Fitzgerald, 35:10-23.

⁴⁹ Ex. 13, Deposition of Dr. Elizabeth Mueller, 86:22-87:6.

II. Reference to Mrs. Huskey's Difficult Childbirth is Highly Prejudicial

Even if reference to Mrs. Huskey's difficult childbirth has a scintilla of probative value, that value is substantially outweighed by the dangers of unfair prejudice, confusing the issues, and misleading the jury. Thus, the evidence should be excluded under Fed. R. Evid. 403. Defendants will inevitably draw attention to Mrs. Huskey's medical history, but they should not be permitted to suggest additional causes of injury without a basis for doing so. Allowing Defendants to introduce evidence of Mrs. Huskey's difficult delivery will confuse the jury into believing that difficult childbirth is a cause of Mrs. Huskey's pain when no expert testimony connects the two issues. As such, any reference to Mrs. Huskey requiring the use of forceps or having a difficult childbirth should be excluded.

MOTION IN LIMINE NO. 9: To Exclude Testimony and Evidence Relating to Plaintiff's Prior Diagnosis or Treatment of Trichomoniasis, a Sexually Transmitted Infection

Plaintiff respectfully moves the Court under Rules 401 and 403 to preclude any testimony regarding Plaintiff's prior diagnosis or treatment of Trichomoniasis, a common and curable sexually transmitted infection. The necessity for Plaintiffs' motion is made clear by Defendants' questioning of Mrs. Huskey on the subject during her deposition.⁵⁰ Nobody, including Defendants' expert witnesses, has even attempted to relate this disease to her current injuries, and this evidence will only serve to unfairly prejudice Plaintiffs or mislead the jury.

I. No Relevant Connection Between Trichomoniasis and Plaintiff's Injury

First, any reference to Plaintiff's Trichomoniasis is completely irrelevant to the facts at issue in this case; namely: Jo Huskey's experience with the TVT-O device. Courts have held that sexually transmitted infection evidence is only admissible under Rule 401 in a product liability action if the Defendant can link the condition to a material issue in the case. In *Garrett v. Money*,

⁵⁰ Ex. 6, Mrs. Huskey Dep. at 92:11-95:1.

the defendant was permitted to introduce evidence of the plaintiff's sexually transmitted disease *only because* the defendant's expert witness testified that the plaintiff's STD could be an alternate cause of her injuries.⁵¹

As such, for evidence of Mrs. Huskey's Trichomoniasis to be relevant to an issue material to the case, Defendants' would first have to provide expert testimony of a relevant long-term effect of Trichomoniasis. Next, Defendants' experts would have to explain the similarities of those effects to the injuries sustained by the Mrs. Huskey. The experts would then have to opine that the Trichomoniasis caused Mrs. Huskey's injuries. Finally, that opinion would have to meet the standard for scientific reliability.⁵² Defendants' experts have not done any of that in this case. In fact, they do not even mention Trichomoniasis.

In this case, Mrs. Huskey was diagnosed, treated, and completely cured of the Trichomoniasis years before having Defendant's TVT-O sling implanted.⁵³ There is no evidence in the record to suggest that Mrs. Huskey suffered from Trichomoniasis during the timeline of events material to the issues of this case. Additionally, there are no known long-term effects of Trichomoniasis⁵⁴—it is very common and easily cured by a single seven-day treatment.⁵⁵

Defendants' experts have not testified to any scientific connection between Plaintiff's Trichomoniasis and her injuries, nor have the experts even claimed the Trichomoniasis is related in any way to the present case. As Defendants' expert witnesses do not even attempt to establish the necessary direct link between the disease and any material issue in the case, such evidence is irrelevant and inadmissible.⁵⁶

⁵¹ No. 94-3053, 1994 U.S. App. LEXIS 30609 at *17 (6th Cir. October 28, 1994).

⁵² As set out in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

⁵³ Ex. 6, Mrs. Huskey Dep. at 93:1-93:16.

⁵⁴ See Gerald L. Mandell et al., *Principles and Practice of Infectious Diseases* 2116 (3rd ed. 1990).

⁵⁵ Information available at <http://www.cdc.gov/STD/trichomonas/default.htm>. Also, see *Garrett v. Money*, 1994 U.S. App. LEXIS 30609, 17 (6th Cir. 1994).

⁵⁶ *Garrett*, 1994 U.S. App. LEXIS 30609 at 17.

II. Trichomoniasis Evidence Will Prejudice Plaintiffs and Confuse the Jury

Furthermore, the danger that evidence of Mrs. Huskey's prior Trichomoniasis will mislead the jury or unfairly prejudice her substantially outweighs any probative value such evidence may have. The Federal Rules of Evidence caution against admitting evidence regarding a victim's past sexual history or sexual predisposition where it is not relevant.⁵⁷ Indeed, several courts have recognized that evidence of a venereal disease or a sexually transmitted disease as "highly inflammatory."⁵⁸ For example, the Iowa Supreme Court has held that any evidence relating to a sexually transmitted disease fails to "reach a level of probative force to warrant the inflammatory and prejudicial impact upon...the proceeding."⁵⁹ "There [is] just too much danger that...STD evidence would brand [the subject] as promiscuous in the eyes of the jury and for that reason [is] not worthy of belief. STD evidence would (1) potentially result in harassing, annoying, and humiliating [her]; (2) be time-consuming; and (3) would distract the inquiry by focusing on [her] conduct rather than [the defendant]."⁶⁰

This evidence will also mislead the jury. Without expert testimony to demonstrate a scientific link between the disease and Plaintiff's injuries, this evidence invites jurors to draw their own conclusions about how the Trichomoniasis may have affected Plaintiff's injury, without any scientific basis to reach such a conclusion. Such an inquiry would take the jury's focus away from the central issue in the case, which is *the Defendants'* role in Mrs. Huskey's injuries.

For these reasons, any evidence as to Mrs. Huskey's Trichomoniasis, suffered many years ago and long since cured, should be excluded.

⁵⁷ *United States v. Bahr*, 2011 U.S. Dist. LEXIS 68197, 6 (M.D. Ala. 2011).

⁵⁸ See *State v. Knox*, 536 N.W.2d 735, 741 (Iowa 1995), *State v. Ridgeway*, 583 N.E.2d 1123, 1124-25 (Ohio Ct. App. 1990), *State v. Ervin*, 723 S.W.2d 412, 415 (Mo. Ct. App. 1986).

⁵⁹ *State v. Mitchell*, 568 N.W.2d 493, 499 (Iowa 1997).

⁶⁰ *Id.*

MOTION IN LIMINE NO. 10: To Exclude Reference to TVT-O Being the “Gold Standard”

I. Reference to the TVT as the “Gold Standard” is Irrelevant.

Defendants’ reference to the TVT device as the “gold standard” for treatment of stress urinary incontinence (“SUI”) is irrelevant under Fed. R. Evid. 401 for purposes of determining whether the TVT-O is a safe and effective product. While Plaintiffs are aware of this Court’s ruling in *Lewis v. Ethicon*⁶¹ (allowing Ethicon to introduce evidence related to the TVT as the gold standard for treatment of SUI), the product at issue in Mrs. Huskey’s case is the TVT-O; thus, this Court’s prior ruling is not necessarily applicable in this case, as explained below.

First, there is no consensus that the “gold standard” for a particular medical treatment equates to the safest and most effective treatment. Testimony from Ethicon’s own experts reveals that the “gold standard” is simply the most commonly used or accepted way to treat a patient—not the best way to treat a patient. As Dr. Weber admitted: “when a scientist talks about a gold standard, it’s not a gold standard. It’s what has become the most commonly used or the most widely accepted way of doing something, a diagnosis, treatment.”⁶² Likewise, Ethicon Medical Director Dr. David Robinson stated that “[‘gold standard’] is not a legal definition or even a medical definition.”⁶³ Without more, the idea that a medical treatment may be “commonly used” or “widely accepted” has no bearing on whether that treatment is safe and effective.

Deposition testimony from Dr. Denise Elser, another Ethicon expert, reveals the failure of the term “gold standard” to take into account specificity. Indeed, when asked which midurethral sling is considered the gold standard for treating SUI, Dr. Elser could not pinpoint a particular sling. She agreed that there are a number of midurethral slings made by different

⁶¹ Memorandum Opinion and Order (Motions in Limine), Dkt. 250, p. 5, February 5, 2014.

⁶² Ex. 14, Deposition of Dr. David Weber, p. 110:2-25.

⁶³ Ex. 15, Deposition of David Robinson, 788:3-9 (Vol. II, 7/25/2013) and 1153:5-14 (Vol. III, 9/11/2013).

companies, with different characteristics, weights, and pore sizes. Dr. Elser further admitted that she could not cite to societies/organizations that asserted the *TVT-O* is the gold standard treatment for SUI.⁶⁴

Dr. Harry Johnson similarly stated that the *TVT-O* has not been specifically called the “gold standard” for SUI. Rather, he explained, the phrase applies to midurethral slings generally.⁶⁵ He agreed that mini-slings and the OB Tape are both midurethral slings; however, he also acknowledged that the OB Tape sling is no longer on the market.⁶⁶ Considering at least one of these midurethral slings is no longer on the market, the application of the term “gold standard” is problematic. Dr. Pramudji’s deposition testimony in the *Lewis* case echoes that of Dr. Elser and Dr. Johnson. She testified that the term “gold standard” applied to all synthetic midurethral retropubic and obturator tapes.⁶⁷ Because the term “gold standard” may encompass any number of products, without regard to whether a product is the safest, most effective treatment for SUI, reference to the *TVT-O* as the “gold standard” becomes irrelevant.

II. Reference to the *TVT-O* as the “Gold Standard” is Highly Prejudicial.

Ethicon’s reference to *TVT-O* as the “gold standard” is misleading, highly prejudicial to Plaintiffs, and would likely confuse the jury. Therefore, such reference should be excluded under Fed. R. Evid. 403. Statements advocating the gold standard are subject to significant misinterpretation. Indeed, an article in the British Medical Journal (BMJ) explains why the phrase is misleading—emphasizing that *medical scientists* have become “confused about the true meaning of the term gold standard” and believe the term “denotes the best standard in the

⁶⁴ Ex. 16, Deposition of Dr. Denise Elser, 181:20-185:20.

⁶⁵ Ex. 17, Deposition of Dr. Harry Johnson, 152:6-153:12.

⁶⁶ *Id.*

⁶⁷ Ex. 18, Deposition of Dr. Christina Pramudji (1/10/14), 190:7-12 (taken in *Lewis v. Ethicon*).

world,” which is incorrect.⁶⁸ If medical scientists are confused and misled by the term, surely a jury would be also.⁶⁹ Another BMJ article warns that gold standards are almost always “never reached,” and finds that the use of the phrase is subject to “considerable criticism.”⁷⁰ The author emphasizes that the phrase “gold standard” is dangerous because of the “certainty implied” and advocates that “because the phrase [“gold standard”] smacks of dogma its use should be discontinued in medical science.”⁷¹ Likewise, reference to the TVT-O as the gold standard lacks certainty and would only mislead and confuse a jury.

MOTION IN LIMINE NO. 11: To Exclude Evidence of AUGS-SUFU Position Statement

Plaintiffs move to exclude any evidence or reference to the January 3, 2014 AUGS-SUFU Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence (the “Statement”).⁷² Plaintiffs’ motion is based on Fed. R. Evid. 401, 402, 403, 702, 801 and 802.

The Statement was prepared by individuals associated with mesh manufacturers and was intended, in part, to provide a “defense” in mesh litigation, to combat plaintiff’s lawyers, and specifically, to assist Ethicon.⁷³ Other goals of the Statement were “to prepare materials (e.g., a tool kit) for our members to help them with the unbalanced anti-MUS message confronting them

⁶⁸ Claassen, Jorgen A.H.R., “The Gold Standard: Not a Golden Standard.” BMJ. May 14, 2005; 330(7500): 1121, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC557893/>.

⁶⁹ Such testimony would inevitably lead to a “trial within a trial” concerning issues such as: the definition of “gold standard” as it relates to treatment for SUI; whether all mid- or suburethral slings are entitled to that designation; which brands or manufacturer’s products are the “gold standard”; when TVT became the “gold standard,” if it did at all; and, whether Ethicon’s branding of TVT resulted in the product’s designation as the “gold standard” treatment for SUI.

⁷⁰ Duggan, P. Finbarr., “Time to Abolish the ‘Gold Standard.’” BMJ. Jun 13, 1992; 304(6841): 1568–1569 available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1882438/pdf/bmj00077-0054c.pdf>.

⁷¹ *Id.*

⁷² Ex. 19, January 3, 2014 American Urogynecological Society (AUGS)-Society of Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction (SUFU) Position Statement.

⁷³ Ex. 20, Deposition of Charles Nager, M.D. at 76-80; 87; 92; 119-120, 128-131; 160-161; 248-251 (June 10, 2014); Ex. 21, Dec. 27, 2013 Email chain between authors of Statement, NAG00145-NAG00147; Ex. 22, January 6, 2014 email chain from Charles Nager to Kimberly Hoggatt, NAG00106-NAG00107, at p. 2; Ex. 23, Deposition of Dennis Miller, M.D., Vol. II, at 352:24-354:16; 380:3-381:5; Ex. 24, 12/5/13 Meeting Notes, MIL00053-54, at p. 2.

daily from the media” and to “develop a position statement, frequently asked questions, and/or talking points.”⁷⁴

The Statement was authored by Drs. Charles Nager, Paul Tulikangas, Dennis Miller, Eric Rovner and Howard Goldman.⁷⁵ Almost every one of these individuals is closely associated with mesh manufacturers. The authors’ conflicts of interest were not disclosed in the initial Statement.⁷⁶ Dr. Nager was a former paid speaker and preceptor for Ethicon.⁷⁷ Dr. Goldman is a key opinion leader for American Medical Systems, Inc. (“AMS”).⁷⁸ Dr. Miller, who serves as a consultant for Ethicon⁷⁹ and key opinion leader for Boston Scientific Corp. (“BSC”), assisted BSC with the FDA. He invented the Pinnacle product, was co-inventor of the Uphold product, and received royalties from BSC for both products.⁸⁰ He also opposed the California Medical Association’s contemplated ban on mesh products.⁸¹ Dr. Rovner is a key opinion leader for AMS.⁸² According to Dr. Rovner, one goal of the Statement was to protect “colleagues from medico-legal problems.”⁸³ While preparing the Statement, Dr. Nager conferred with Kim Hoggatt (an Ethicon sales representative) to get information from the mesh manufacturing industry to be used in the statement.⁸⁴ During his deposition, Dr. Nager admitted that the Statement could be self-serving because doctors would be using it to defend their right to perform surgeries in which they have an economic stake.⁸⁵

⁷⁴ Ex. 23 at 349:22-351:2; 351:3-352:4; Ex. 25 November 27, 2013 email from Charles Nager MIL00009.

⁷⁵ Ex. 19 (Position Statement) at p. 3. Dr. Nager is President of AUGS. Ex. 20 (Nager Dep.), at 32-33.

⁷⁶ Ex. 20 (Nager Dep.), at 273.

⁷⁷ *Id.* at 318-319.

⁷⁸ Ex. 26, MDL AMS D1180968-R and MDL AMS D6891562-571.

⁷⁹ *See, e.g.*, Ex. 27, AUGS Health Science Corporate Membership Application, ETH.MESH.00803101-12.

⁸⁰ Ex. 23 (Miller Dep.) at 287:17-288:19; 322:12-322:14, 328:16-328:33.

⁸¹ *Id.* at 329:22-330:5; 336:24-337:10.

⁸² Ex. 28, MDL AMS D3807975-977; MDL AMS D2239580; MDL AMS D3926999-7000.

⁸³ Ex. 29, November 27, 2013 email from Eric Rovner MIL00015; Ex. 23 (Miller Dep.) at 356:20-357:18.

⁸⁴ Ex. 21 (NAG00145-NAG00147).

⁸⁵ Ex. 20 (Nager Dep.) at 93.

In addition authors' conflicts of interest, AUGS itself is closely related to mesh manufacturers.⁸⁶ Ethicon is a member of AUGS, as are other manufacturers of mid-urethral slings, including Bard, BSC, AMS and Coloplast.⁸⁷ Manufacturers utilize their affiliations with AUGS to promote their products to members.⁸⁸ The Position Statement did not disclose these manufacturer/corporate memberships.⁸⁹

The Statement was crafted by key opinion leaders to vindicate the conduct of mesh manufacturers (including Ethicon) and to defend manufacturers in product liability actions. This Statement is entirely self-serving, and has no tendency to make more probable any fact of consequence to the case. Therefore the Statement is irrelevant and inadmissible under Rules 401 or 402. Additionally, any marginal relevance of such evidence is substantially outweighed by unfair prejudice, confusion of the jury, and waste of time. *See* Fed. R. Evid. 403. The Statement also fails to meet the requirements of Rule 702 and *Daubert*. The statement fails to meet these requirements because it is nothing more than propaganda by these key opinion leaders for mesh manufacturers.⁹⁰ Finally, the Statement is inadmissible hearsay under Rule 802 and is not subject to any exceptions under Rules 803 or 804.

In *Jones v. Ford Motor Co.*,⁹¹ the Court excluded a NHTSA report because the report was prepared with inaccurate information supplied to the NHTSA by Ford. The court concluded that cross-examination on the negative issues related to the report would confuse the jury, divert the jury's attention, and waste time in violation of Rule 403.⁹² The Court also concluded that the

⁸⁶ Ex. 30, MDL AMS DD 10466577-578; MDL AMS D7478447-457; MDL AMS D1359933-R-936-R; MDL AMS D7141560-613; MDL AMS D1517702-R-708-R and MDL AMS D757740-743.

⁸⁷ Ex. 20 (Nager Dep.) at 349-353; Ex. 31, AUGS website listing of Corporate Members.

⁸⁸ Ex. 20 (Nager Dep.) at 349-353; *see also* Ex. 27, AUGS Health Science Corporate Membership Application

⁸⁹ Ex. 20 (Nager Dep.) at 352-353.

⁹⁰ Dr. Nager testified that the assertions in the statement were drafted and then they sought support for each assertion. Ex. 20 (Nager Dep.) at pp. 262-265.

⁹¹ 320 F. Supp. 2d 440 (E.D. Va. 2004)

⁹² *Jones*, 320 F. Supp. 2d at 451-52.

NHTSA report was not trustworthy under Rule 803(8)(C) because it was grounded heavily on information supplied by Ford.⁹³ In *Bright v. Firestone Tire & Rubber Co.*,⁹⁴ the Court affirmed the exclusion of a Congressional Report under Rule 803(8)(C) and Rule 403. The district court properly excluded the report because it was not trustworthy, and because its prejudicial effect substantially outweighed its probative value.⁹⁵ The court noted that “it would be extremely difficult and time-consuming to evaluate the report’s trustworthiness and all the data on which it was based.”⁹⁶

For the reasons above, this Court should exclude from evidence any reference to the Statement under Rules 401, 402, 403, 702 and 802.

MOTION IN LIMINE NO. 12: To Exclude Evidence Regarding the Preservation of Jo Huskey’s Explanted Mesh

Throughout this case, Defendants continue to claim that Plaintiffs “failed to preserve” Jo Huskey’s explanted mesh. Defendants do not, however, have any merit for these claims; and further, it is entirely irrelevant to either party’s ability to prove, or defend, their case under Illinois law. Any reference to Plaintiffs’ so-called “failure to preserve” Mrs. Huskey’s mesh is unnecessary, irrelevant, highly prejudicial, and should be excluded at trial pursuant to Federal Rules of Evidence 402 and 403.

I. Disposal of a Defective Product is Not Relevant to the Claims or Defenses in this Case under Illinois Law.

Illinois law (which will apply to the substantive claims in this case) is clear that the defective product at issue is not necessary in a products liability case and sufficient evidence can

⁹³ *Id.* at 452.

⁹⁴ 756 F.2d 19 (6th Cir. 1984).

⁹⁵ *Bright*, 756 F.2d at 22-23.

⁹⁶ *Id.* at 23.

be presented in its absence.⁹⁷ Significantly, Illinois courts have explicitly held that the defective product is not needed when the case involves an implantable medical device (such as the TVT-O mesh), because a plaintiff may use alternative evidence to prove that a device failed to perform as reasonably expected.⁹⁸

II. Ethicon Improperly Seeks to Insert Attorney Conduct Into This Case.

The mesh at issue was destroyed while in the possession of the hospital after it had been explanted from Mrs. Huskey. There has been no showing of willful or bad faith conduct that would support an inference of spoliation.⁹⁹ However, Defendants seek to insert an unsupported inference of attorney misconduct—and encourage the jury’s imagination to run wild based upon that unsupported inference. To allow Defendants do so serves no purpose other than to severely prejudice Plaintiffs at trial. Moreover, Defendants’ continuous allegations regarding the preservation of the mesh are nothing more than Ethicon’s attempt to confuse jurors into thinking attorney conduct is an issue at trial. As the commentary to F.R.E. 403 states, “unfair prejudice is an undue tendency to suggest decision on an improper basis, commonly, though not necessarily, an emotional one.”¹⁰⁰ There is a very real risk that this type of evidence, as framed by Defendants, can cause confusion and an emotional response from jurors. Because this risk of unfair prejudice substantially outweighs any legitimate use of the evidence—and because its admission will only create a sideshow at trial—it should be excluded.

⁹⁷ *Braverman v. Kucharik Bicycle Clothing Co.*, 287 Ill. App. 3d 150, 154 (Ill. App. Ct. 1st Dist. 1997) (citing *Mateika v. La Salle Thermogas Co.*, 94 Ill. App. 3d 506, 510 (Ill. App. Ct. 3d Dist. 1981)); see also *Loren Neighbors v. The City of Sullivan*, 334 N.E.2d 409, 411 (Ill. App. Ct. 4th Dist. 1975) (holding that the defective product need not be produced at trial when a defect can be shown by circumstantial evidence.).

⁹⁸ *DiCosolo v. Janssen Pharms., Inc.*, 951 N.E.2d 1238, 1204-46 (Ill. App. Ct. 1st Dist. 2011); see also *Samansky v. Rush*, 208 Ill. App. 3d 377 (Ill. App. Ct. 1st Dist. 1990).

⁹⁹ See Pretrial Order #100, 2:12-md-2327, Dkt. No. 1069 (this Court’s prior ruling regarding Ethicon’s spoliation of documents).

¹⁰⁰ Fed. R. Evid. 403 Advisory Committee Note (1972).

For the reasons stated above, Plaintiffs respectfully request that this Court enter an order precluding evidence at trial regarding the preservation of Jo Huskey's explanted mesh.

MOTION IN LIMINE NO. 13: To Exclude Certain Testimony Of Treating Physician, Elizabeth Mueller, M.D.

Plaintiffs move to limit the testimony of Elizabeth Mueller, M.D. ("Dr. Mueller") to the scope of her treatment of Mrs. Huskey. During her deposition, Dr. Mueller offered several expert opinions that have nothing to do with her treatment of Mrs. Huskey; yet, Dr. Mueller has not been designated as retained expert, and she has not submitted an expert report, as required by Rule 26(a)(2)(B). Thus, she may only testify to matters related to her treatment of Mrs. Huskey. Plaintiffs further move to exclude as unreliable Dr. Mueller's testimony as to the cause of Mrs. Huskey's injuries.

Dr. Mueller saw Mrs. Huskey only once—on May 16, 2013¹⁰¹—to assess Mrs. Huskey's pelvic pain following her mesh surgery and partial excision, and to determine whether her pain could be alleviated surgically.¹⁰² Dr. Mueller, after limited examination, found it could not.¹⁰³ Dr. Mueller did not recall her appointment with Mrs. Huskey,¹⁰⁴ read only operative notes from Mrs. Huskey's excision procedure and none from her implant,¹⁰⁵ and did not know Mrs. Huskey's medical history (including any medications she was taking).¹⁰⁶

Despite this very limited involvement in Mrs. Huskey's treatment—and lack of knowledge of her condition and injuries—Dr. Mueller testified at her deposition regarding: (1) her general clinical experience with Ethicon and other transvaginal mesh devices;¹⁰⁷ (2) the

¹⁰¹ See Ex. 13, Dr. Mueller Dep. (10/23/13) at 5:13-14; 57:5-7, 12-15.

¹⁰² *Id.* 64:2-6; 64:17-24; 78:15-79:14.

¹⁰³ *Id.* 78:15-79:14.

¹⁰⁴ *Id.* 8:19-23.

¹⁰⁵ *Id.* 90:19-91:16.

¹⁰⁶ *Id.* 95:25-96:3.

¹⁰⁷ *Id.* 25:20-29:7.

findings from her practice’s clinical study on Ethicon mesh devices;¹⁰⁸ (3) her general experience with SUI treatments and her opinion that mesh surgeries are preferable;¹⁰⁹ (4) her patients’ “good level of satisfaction” with TVT devices;¹¹⁰ (5) the impact generally of SUI on women’s lives;¹¹¹ (6) her training to implant mesh devices including Ethicon products;¹¹² (7) her general experience treating women with mesh complications, including erosions, and that she continues to use mesh devices;¹¹³ (8) statistics her practice keeps about mesh-related complications and revisions she performs;¹¹⁴ (9) her opinion that such complications are unrelated to mesh devices or surgical competency;¹¹⁵ (10) complications she has experienced with fascial procedures;¹¹⁶ (11) her review of literature regarding TVT products;¹¹⁷ (12) her opinion that mesh surgeries are “easier” with higher cure rates;¹¹⁸ (13) opinions about “instructions for use” for mesh devices or the positions of the AUGS and/or the FDA concerning mesh products,¹¹⁹ and (14) her opinion that mesh does not cause chronic pain but only acute, episodic pain.¹²⁰

Dr. Mueller’s testimony regarding *all* of the foregoing should be excluded because it is outside the scope of her treating relationship with Mrs. Huskey. In addition, some of Dr. Mueller’s opinions are also inadmissible because she did not rely on proper methodology.

¹⁰⁸ *Id.* 9:3-13:12; 21:21-25:19; 28:15-21; 33:17-34:19.

¹⁰⁹ *Id.* 18:16-25:19.

¹¹⁰ *Id.* 29:8-23.

¹¹¹ *Id.* 32:5-33:15.

¹¹² *Id.* 34:20-36:12.

¹¹³ *Id.* 36:13-38:2; 39:17-41:14; 47:24-48:10.

¹¹⁴ *Id.* 41:15-47:11.

¹¹⁵ *Id.* 47:12-22.

¹¹⁶ *Id.* 48:11-49:6.

¹¹⁷ *Id.* 49:16-24.

¹¹⁸ *Id.* 50:9-52:17.

¹¹⁹ *Id.* 52:18-53:14.

¹²⁰ *Id.* 106:18-107:21.

This Court and others have noted that a treating physician such as Dr. Mueller may testify *only* to matters within the scope of her treatment of a patient/plaintiff.¹²¹ Anything beyond that scope is considered expert opinion for which the physician must submit a proper expert report under Rule 26(a)(2)(B).¹²² Dr. Mueller has not submitted an expert report in this case; therefore, Dr. Mueller's opinions may include only those items directly related to her limited treatment of Mrs. Huskey—and may not include any of the extraneous and irrelevant opinions above.¹²³

Finally, Dr. Mueller's opinions that do not relate to her examination should be dismissed as unreliable because she did not conduct an appropriate differential diagnosis.¹²⁴ She did not assess Mrs. Huskey's symptoms "and then eliminate[e] each...potential cause [] until [she reached] one that cannot be ruled out or determin[e] which of those that cannot be excluded [was] the most likely."¹²⁵ Dr. Mueller's examination of Mrs. Huskey revealed tenderness and a "firm area" on the left wall of Mrs. Huskey's vagina.¹²⁶ Still, Dr. Mueller concluded that her symptoms were unrelated to the mesh implant.¹²⁷ She failed to attribute the tenderness in Mrs. Huskey's vaginal wall or the firm spot she found there to *any cause*, thus eliminating mesh as a cause without explanation.¹²⁸ By her own admission, Dr. Mueller did not even have a radiologist read Mrs. Huskey's ultrasound.¹²⁹ And Dr. Mueller was only looking to answer one "very

¹²¹ See *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 615 (S.D.W.Va. 2013) ("The inquiry is whether the treating physician's testimony addresses knowledge gained and opinions formed during the course of treatment; or whether the treating physician seeks to offer opinions which address information outside the scope of treatment."); see also, *Hinkle v. Ford Motor Corp.*, C. A. No. 3:11-24-DCR, 2013 WL 1992834 at *5-6 and nn. 4, 7 (E.D.Ky. May 13, 2013); *Bekaert Corp., v. City of Dyersburg*, 256 F.R.D. 573, 575-76 (W.D.Tn. 2009).

¹²² See *National R.R. Passenger Corp., v. Railway Express, LLC*, 268 F.R.D. at 211, 216 (D.Md. 2010) ("a party may not circumvent the requirements of Rule 26 by employing a witness like a treating physician who treated an injured party, to provide testimony extending into a classic expert opinion regarding causation and prognosis. ").

¹²³ See *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 616.

¹²⁴ See *Zellers v. Nox Tech Northeast, LLC*, 895 F. Supp. 2d 734, 742 (E.D.Va. 2012) ("[T]he opinions of Plaintiff's treating physicians are not based on reliable application of the differential diagnosis methodology.");

¹²⁵ *Id.*

¹²⁶ Ex. 13 (Dr. Mueller Dep.) at. 62:2-11; 75:7-11.

¹²⁷ *Id.* 66:12-16.

¹²⁸ *Id.* 75:7-21; 76:6-78:4; 78:20-79:20.

¹²⁹ *Id.* 81:17-25.

specific question” when she examined Mrs. Huskey.¹³⁰ This is an insufficient differential diagnosis under the law and Dr. Mueller’s opinion that Mrs. Huskey’s pain was not caused by mesh should be excluded.

MOTION IN LIMINE NO. 14: To Exclude Evidence of Defendant’s Prior or Unrelated “Good Acts” or “Good Reputation”

Defendants may attempt to offer evidence of testimony regarding prior acts of public benefit that are unrelated to the TVT-O or this case (*e.g.* community employment, charitable donations of money and medicine and medical contributions such as the development of new products) in order to convey a general “good company” reputation. Pursuant to Federal Rules of Evidence 402 and 403, this type of evidence is not relevant to Plaintiffs’ claims and is unduly prejudicial. Additionally, because Defendants could only be attempting to show that they were acting in accordance with their “good” character, this evidence is inadmissible under Rules 402, 403, and 404.

I. “Good Acts” and “Good Reputation” Testimony or Evidence Is Irrelevant

To be admissible, evidence must be relevant.¹³¹ Relevant evidence means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more or less probable than it would be without evidence.¹³² Evidence of “good acts,” “good reputation” or contributions to society is irrelevant to any of Plaintiffs’ claims in this case. Even if such “good company” arguments were accepted as true, they would have no effect on the ultimate issue in this case—whether Defendants’ TVT-O device injured Mrs. Huskey. This evidence does no more than provide unrelated events in the company’s history with the intent of capitalizing on the favorable nature of the prior, unrelated good acts.

¹³⁰ *Id.* 80:17-23.

¹³¹ Fed. R. Evid. 402.

¹³² Fed. R. Evid. 401.

Without a showing of any relevance to Defendants' liability for Plaintiff's injuries, this evidence should be excluded.

II. "Good acts" and "Good Reputation" Testimony or Evidence is Overly-Prejudicial

Evidence of "good acts" or "good reputation" should also be excluded under Federal Rule of Evidence 403. The evidence has low probative value, if any; it is also unduly prejudicial, confusing as to the issues, and likely to mislead the jury. Evidence of Defendants' unrelated "good acts" likely would mislead the jury into believing that Defendants do not have the propensity to do wrong. As the commentary to Rule 403 states, "unfair prejudice is an undue tendency to suggest decision on an improper basis, commonly, though not necessarily, an emotional one."¹³³ As the Fourth Circuit has written: "[f]oremost among those dangers is the risk of 'unfair prejudice,' which refers to an undue tendency of evidence to influence a jury to make a decision for reasons unrelated to the probative value of the evidence."¹³⁴ These "good acts" have no bearing on Defendants' liability,¹³⁵ and therefore, can only be used to evoke admiration for the company's history and past good deeds—with the hope of improperly influencing the jury's decision as to liability.

Admission poses a risk that the "emotions of the jury will be excited to irrational behavior, and that this risk is disproportionate to the probative value of the offered evidence."¹³⁶ Because the risk of unfair prejudice outweighs the legitimate uses of the evidence, such evidence should be excluded.

¹³³ Fed. R. Evid. 403 Advisory Committee Note (1972).

¹³⁴ *Carnell Constr. Corp. v. Danville Redevelopment & Hous. Auth.*, 745 F.3d 703, 719 (4th Cir. 2014) quoting *United States v. Mohr*, 318 F.3d 613, 620 (4th Cir. 2003).

¹³⁵ A factor courts have considered in evaluating the probative value of evidence is whether the evidence is necessary to defendant's case. *Campus Sweater & Sportswear Co. v. M.B. Kahn Constr. Co.*, 515 F. Supp. 64, 91 (D.S.C. 1979). Here, issues of causation, liability, or damages are unaffected by evidence of Defendants' prior good acts.

¹³⁶ *United States v. Lentz*, 524 F.3d 501, 525 (4th Cir. 2008).

III. “Good Acts” and “Good Reputation” Testimony is Improper Propensity Evidence

Under Federal Rule of Evidence 404(a), evidence of a party’s character is not admissible to prove that on a particular occasion the party acted in accordance with that character or trait. Fed. R. Evid. 404(a). Moreover, proof of other specific acts is inadmissible. Fed. R. Evid. 404(b). Defendants “cannot prove [a] pertinent character trait (of being ‘good’) by offering evidence of specific instances of good conduct.” *United States v. Crockett*, 586 F. Supp. 2d 877, 884 (E.D. Mich. 2008).¹³⁷

This Court should exclude evidence of Defendants’ prior good acts or business conduct when it is used to show conformity with such behavior on this occasion. The fact that Defendants purportedly employed individuals in the community, made charitable contributions, or distributed some medical benefit to society does not bear on Defendants’ liability with respect to injuries suffered by Plaintiffs. These specific acts of good character are inadmissible under Rule 404(b) to prove Defendant’s action in conformity therewith.

MOTION IN LIMINE NO. 15: To Exclude Testimony and Evidence Relating to Personal Experiences (and Personal Preferences) of Defendant’s Employees and Expert Witnesses with Implanted TVM Devices

Plaintiffs respectfully move the Court under Rules 401, 403, 701 and 702 to preclude any retrospective or hypothetical testimony regarding Defendants’ employees or expert witness’ willingness to have the TVT-O sling implanted in themselves (or their family members) as a remedy for stress urinary incontinence (“SUI”).

¹³⁷ In deciding a motion in limine to exclude references to the defendant’s prior legitimate business acts, a court precluded defendant from introducing extrinsic evidence of purportedly legitimate business activities in order to negate evidence of his fraudulent intent with respect to the case at hand. *United States v. Ellisor*, 522 F.3d 1255, 1270 (11th Cir. 2008). The court found that “evidence of good conduct is not admissible to negate criminal intent.” *Ellisor*, 522 F.3d at 1270. See *United States v. Camejo*, 929 F.2d 610, 613 (11th Cir. 1991); see also *Crockett*, 586 F. Supp. 2d at 884 (holding that defendant will not be permitted to prove a pertinent character trait by offering evidence of specific instances of good conduct); *United States v. Hill*, 40 F.3d 164, 168 (7th Cir. 1994).

Defendants may seek to introduce testimony from their employees, other lay witnesses, or their experts regarding the witness' personal experiences with pelvic mesh devices, or those of a friend or family member. Similarly, Defendants may elicit testimony by asking: *if* the witness (or a family member) were suffering from SUI, would the witness prefer that the TVT-O sling be implanted? The necessity for Plaintiffs' motion is evident from the testimony of Ethicon employee Meng Chen—stating that if she developed SUI, she would have no hesitation about having a TVT-O sling implanted, or about recommending that a family member do the same.¹³⁸

I. Other Individuals' Past or Present Personal Experiences with TVM Devices

First, any reference to a witness's (or a family member's) past or present experiences with pelvic mesh devices, including the TVT-O sling, is completely irrelevant to the issue in this case: Jo Huskey's experience. Indeed, these types of statements should be excluded because, at best, they are "clearly collateral to the central issues of the trial."¹³⁹ Moreover, no medical records have been produced regarding these other individuals, no depositions have been taken, and Plaintiffs are left completely without the ability to investigate or challenge any claims of successful treatment and recovery. Indeed, to allow witnesses to discuss other individuals' experiences and outcomes would require the parties to delve into the facts of those surgeries. It would call for additional discovery from non-parties and their treating physicians. To do so would only create a side-show that would surely mislead and confuse the jury—and waste the time of everyone involved. For this reason, even if the Court were to determine that these statements regarding other individuals' experience with the TVT-O (or other pelvic mesh) are in

¹³⁸ Ex. 32, Deposition of Meng Chen (10/30/13) (Vol. II) at 318:15-319:6.

¹³⁹ *Pacific Inst. for Research & Evaluation v. Procter & Gamble Co.*, 1993 U.S. App. LEXIS 34633, 4 (9th Cir. 1993); *see also Brown v. Sierra Nevada Mem. Miners Hosp.*, 849 F.2d 1186, 1191–1192 (9th Cir. 1988) (testimony about general personal perceptions was too tenuously relevant to have probative value on issue of racial discrimination).

some way relevant, they create a danger of unfair prejudice and a potential to mislead the jury that substantially outweighs their minimal probative value.¹⁴⁰

II. Testimony that a Witness “Would Have” the TVT-O Implanted

Additionally, *hypothetical* personal preferences are even more tenuous and further lack probative value, as these questions require the witness to opine about an event that has yet to occur. Personal preference statements are not proper fact witness testimony, are excessively speculative, and are too tenuous to have any tendency of making the existence of any fact of consequence in Ethicon’s liability more or less probable than it would be without such testimony.¹⁴¹

Also, hypothetical questions posed to *Ethicon employees* should be excluded on their face under Rule 701, because lay witnesses are barred from answering hypothetical questions.¹⁴² Such testimony is not “rationally based on the witness’s perception,”¹⁴³ but rather is self-serving opinion intended to bolster Ethicon’s defenses. To permit such statements would allow Ethicon’s witnesses to “opine broadly or generally”¹⁴⁴ and to make “meaningless assertions which amount

¹⁴⁰ See Fed. R. Evid. 403.

¹⁴¹ See Fed. R. Evid. 401.

¹⁴² See e.g., *Teen-Ed, Inc. v. Kimball International, Inc.*, 620 F.2d 399, 404 (3d Cir. 1980) (“essential difference” between lay witness testifying under Fed. R. Evid. 701 and qualified expert testifying under Fed. R. Evid. 702 is that “qualified expert may answer hypothetical questions”); *Certain Underwriters at Lloyd’s v. Sinkovich*, 232 F.3d 200, 203-04 (4th Cir. 2000).

¹⁴³ See Fed. R. Evid. 701; see also, *Washington v. Dep’t of Transp.*, 8 F.3d 296, 300 (5th Cir. 1993) (The court properly excluded defendant’s testimony as speculative when he testified as to what he would have done had he seen the warning label on product. Because such testimony would not have been based upon defendant’s perception, but upon his self-serving speculation, the district court did not abuse its discretion in excluding this evidence.); *Kloepfer v. Honda Motor Co., Ltd.*, 898 F.2d 1452, 1459 (10th Cir.1990) (conclusion that speculative lay testimony by the plaintiff--as to whether she would have obeyed a warning--was properly excluded because such testimony would not have been based on the witness’s perception).

¹⁴⁴ *United States v. Hassan*, 742 F.3d 104, 135 (4th Cir. 2014) (Lay witnesses are not entitled to opine broadly or generally.)

to little more than choosing up sides,”¹⁴⁵ in clear violation of Rule 701’s requirement that lay witness opinion testimony be based on personal knowledge¹⁴⁶ and helpful to the fact-finder.¹⁴⁷

And while Ethicon may pose relevant hypothetical questions to its expert witnesses,¹⁴⁸ the testimony must be based on “scientific, technical, or other specialized knowledge and assist the trier of fact.”¹⁴⁹ Personal preference testimony from an expert creates “simply too great an analytical gap between the data and the opinion proffered.”¹⁵⁰ Finally, the extremely limited probative value of these preference statements is substantially outweighed by the danger of unfair prejudice and the risk of misleading the jury.¹⁵¹

For all of these reasons, the Court should exclude any testimony about a witness’s experiences with pelvic mesh devices, or about the witness’s willingness to use or recommend such devices.

This 14th Day of July, 2014

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¹⁴⁵ *United States v. Offill*, 666 F.3d 168, 177-78 (4th Cir. 2011) (quoting Fed. R. Evid. 701, Advisory Committee Note).

¹⁴⁶ *United States v. Perkins*, 470 F.3d 150, 155–156 (4th Cir. 2006) (stating that “lay opinion testimony must be based on personal knowledge”).

¹⁴⁷ See Fed. R. Evid. 701 and Fed. R. Evid. 701 Advisory Committee Note (1972) § 701 App. 01[2]. The Advisory Committee Note to Rule 701, as it was originally proposed, expressly recognized that exclusion on grounds of unhelpfulness would be appropriate for opinions that do little more than tell the finder of fact what result to reach.

¹⁴⁸ See *Sinkovich*, 232 F.3d at 203-04.

¹⁴⁹ See Fed. R. Evid. 702; see also *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147–149 (1999).

¹⁵⁰ *Id.*

¹⁵¹ See Fed. R. Evid. 403.

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CERTIFICATE OF SERVICE

I hereby certify that on July 14, 2014, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive services in this MDL.

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